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Amdt. dated February 20, 2004
Reply to Office Action of October 20, 2003

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Amendments to the Claims:

This listing of claims will replace all prior versions, and listings of claims in the application:

Listing of Claims:

1   1.   (Currently Amended) A computer-implemented method of identifying

2   whether a test subject is suffering from one or more systemic autoimmune diseases selected from

3   the group consisting of systemic lupus erythmatosus, scleroderma, Sjögren's syndrome,

4   polymyositis, dermatomyositis, CREST, and mixed connective tissue disease, said method

5   comprising:

6   (a) receiving a test data set for the test subject, wherein the test data set is

7   obtained ~~from~~ by subjecting a biological sample of the test subject to a set of one or more tests

8   that produce values representing levels of a plurality of autoaintibodies present in the sample

9   such that ~~and wherein~~ the test data set has values representing levels of [[a]] said plurality of

10   autoantibodies;

11   (b) storing a plurality of reference data sets, ~~each reference data set obtained from~~

12   ~~a biological sample of a reference subject known to have a systemic autoimmune disease of~~

13   ~~known identity~~ including i) reference data sets obtained for each of said one or more systemic

14   autoimmune diseases by subjecting biological samples of reference subjects, each known to have

15   one of said one or more systemic autoimmune diseases, to said set of one or more tests, and ii)

16   reference data sets obtained by subjecting biological samples of reference subjects known to not

17   have one of said one or more systemic autoimmune diseases to said set of one or more tests, such

18   that ~~wherein~~ each stored reference data set has values representing levels of [[the]] said plurality

19   of autoantibodies, and wherein each stored reference data set is associated with none, one or

20   more of said systemic autoimmune diseases; [[and]]

21   (c) comparing the test data set and the stored reference data sets by applying a k-

22   nearest neighbor ~~process~~ algorithm to produce a statistically derived decision indicating whether

23   the test subject is suffering from none, one or more of said systemic autoimmune diseases; and

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24   (d) identifying which of said systemic autoimmune diseases the test subject is

25 suffering from if the statistically derived decision indicates that the test subject is suffering from

26 one or more of said systemic autoimmune diseases.

1   2.   (Previously Presented) A method in accordance with claim 1 in which step

2 (c) produces a statistically derived decision indicating whether said test subject is suffering from

3 two of said systemic autoimmune diseases.

1   3.   (canceled)

1   4.   (canceled)

1   5.   (Original) A method in accordance with claim 1 in which said plurality of

2 autoantibodies numbers from 10 to 100 autoantibodies.

1   6.   (Original) A method in accordance with claim 1 in which said plurality of

2 autoantibodies numbers from 15 to 25 autoantibodies.

1   7.   (Previously Presented) A method in accordance with claim 1 in which said

2 plurality of autoantibodies comprises antibodies to at least fifteen of the following antigens:

3   SSA 60,

4   SSA 52,

5   SSB 48,

6   Sm BB',

7   Sm D1,

8   RNP 68,

9   RNP A,

10   RNP C,

11   Fibrillarin,

12   Riboproteins P0, P1, and P2,

13   dsDNA,

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14	Nucleosome,
15	Ku,
16	Centromere A,
17	Centromere B,
18	Scl-70,
19	Pm-Scl,
20	RNA-Polymerases 1, 2, and 3,
21	Th,
22	Jo-1,
23	Mi-2,
24	PL7,
25	PL12, and
26	SRP.

1   8.   (Previously Presented) A method in accordance with claim 1 in which said

2   plurality of autoantibodies comprises antibodies to each of the following antigens:

3	SSA 60,
4	SSA 52,
5	SSB 48,
6	Sm BB',
7	Sm D1,
8	RNP 68,
9	RNP A,
10	RNP C,
11	Fibrillarin,
12	Riboproteins P0, P1, and P2,
13	dsDNA,
14	Nucleosome,
15	Ku,

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16   Centromere A,

17   Centromere B,

18   Scl-70,

19   Pm-Scl,

20   RNA-Polymerases 1, 2, and 3,

21   Th,

22   Jo-1,

23   Mi-2,

24   PL7,

25   PL12, and

26   SRP.

1   9.   (Previously presented) A method in accordance with claim 1 in which said

2 reference data sets represent from 100 to 10,000 biological samples from reference subjects

3 known to have systemic autoimmune diseases of known identity.

1   10.   (Previously presented) A method in accordance with claim 1 in which

2 said reference data sets represent from 200 to 2000 biological samples from reference subjects

3 known to have systemic autoimmune diseases of known identity.

1   11.   (canceled)

1   12.   (Original) A method in accordance with claim 1 in which said biological

2 sample from said test subject is a member selected from the group consisting of serum, plasma,

3 urine, and cerebrospinal fluid.

1   13.   (Original) A method in accordance with claim 1 in which said biological

2 sample from said test subject is serum.

1   14.   (Currently Amended) A method in accordance with claim 1 in which the

2 ~~test data set is~~ <u>one or more tests include a test</u> based on analysis by immunoassay.

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1   15.   (Currently Amended) A method in accordance with claim 1 in which the

2   test data set is one or more tests include a test based on analysis by immunoassay with

3   fluorescence detection.

1   16.   (Currently Amended) A method in accordance with claim 1 in which said

2   one or more systemic autoimmune diseases consists of includes systemic lupus erythmatosus.

1   17.   (Currently Amended) A computer-implemented method of diagnosing

2   whether a test subject is suffering from one or more systemic autoimmune diseases selected from

3   the group consisting of systemic lupus erythmatosus, scleroderma, Sjögren's syndrome,

4   polymyositis, dermatomyositis, CREST, and mixed connective tissue disease, said method

5   comprising:

6   (a) receiving a test data set for the test subject, wherein the test data set [[is]]

7   includes data values obtained by analysis of a biological sample of the test subject and wherein

8   the data values of the test data set has values representing represent levels of each of a plurality

9   of autoantibodies;

10   (b) storing a plurality of reference data sets to a database, wherein [[each]] the

11   reference data set is sets include data values obtained by analysis of [[a]] biological sample of a

12   samples of reference subject subjects each known to have at least one of said one or more [[a]]

13   systemic autoimmune diseases disease of known identity, wherein the data values of each

14   reference data set has values representing represent levels of each of [[the]] said plurality of

15   autoantibodies, and wherein each of the reference data sets is associated has a specific

16   association with one or more of said systemic autoimmune diseases; and

17   (c) applying a k-nearest neighbor process algorithm to the test data set and the

18   reference data sets from the database to produce a statistically derived decision indicating

19   whether the test subject is suffering from one or more of said systemic autoimmune diseases,

20   wherein the statistically derived decision includes an indication of one or more of said systemic

21   autoimmune diseases.

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1   18. (Previously Presented) The method of claim 17, wherein the autoantibody

2 levels in the test and reference data sets are determined using the same multianalyte analysis

3 tests.

1   19. (New) The method of claim 17, wherein the data values obtained for each

2 reference data set and the test data set are each determined simultaneously in an automated test

3 system.

1   20. (New) The method of claim 1, wherein the set of one or more tests are

2 performed substantially simultaneously in an automated test system.